Remarks/Arguments

I. Status of Claims

Claims 5, 9, 11, 13, 15-16, 18, 20, 25 and 26 are currently pending, with claims 1-4, 17 and 21 withdrawn from consideration as drawn to a non-elected invention. Claims 6-8, 10, 12, 14, 19, and 22-24 have previously been canceled. Claims 5 and 13 are amended upon entry of this amendment to put the application in condition for allowance or in better form for consideration on appeal. Accordingly Applicants request entry of this amendment in accordance with 37 CFR §1.116.

II. Rejection under 35 U.S.C. §112, first and second paragraphs

The claims remain rejected primarily because the hybridization conditions specified in part (b) of claims 5 and 13 are said to be indefinite and to encompass sequences with sufficiently low sequence homology to SEQ ID NO:1 such that these claims fail to satisfy the written description requirement. Although Applicants disagree with this conclusion, in order to advance prosecution of important subject matter, claims 5 and 13 have been amended to delete section (b) of claims 5 and 13. These amendments render the rejection of the claims on this basis moot.

The Office Action also says that the recitation of 90% sequence identity in claims 5 and 13 does not have adequate written description because the specification allegedly does not relate the structural features of the polypeptide to its function in binding RANKL. Applicants respectfully disagree. The specification makes clear that soluble forms of RANK, which include the extracellular domain of RANK, can bind RANKL (see, e.g., page 2, lines 13-15) and states that certain soluble forms comprise amino acids 33-213 of SEQ ID NO:2, which is precisely the region specified in what is now part (b) of claims 5 and 13. The specification further states that RANK on osteoclast progenitor surfaces (i.e., the extracellular region of RANK) interacts with RANKL on osteoblasts or stromal cells to cause signaling that results in differentiation of osteoclast precursors into osteoclasts. Thus, soluble RANK can be used to inhibit this interaction. The specification thus does relate the structural features of the specified region of the polypeptide of part (b) of claims 5 and 13 to its function.

As pointed out in the last response, the Written Description Guidelines set forth the appropriate standard for assessing whether the written description requirements have been satisfied. The Guidelines provide that a claim directed to a genus (e.g., part (b) of

claims 5 and 13 as currently amended) can satisfy the written description requirement by, for example, disclosing "relevant identifying characteristics" (Fed. Reg., vol. 66, page 1099 (January 5, 2001)). Examples of such characteristics are said to include: (1) structures or other chemical or physical properties, (2) functional characteristics coupled with a known or disclosed correlation between structure and function, or (3) combinations of such identifying characteristics.

As noted in the last response, the specification and part (b) of claims 5 and 13 as currently amended satisfy the written description requirement by disclosing several relevant identifying characteristics. Specifically, part (b) states that certain soluble RANK polypeptides have greater than 90% sequence identity to a certain defined region of SEQ ID NO:2. As explained above, this specified region corresponds to the extracellular domain that is involved in binding to RANKL. Part (b) as amended thus satisfies the structural criterion of the Guidelines as set forth in (1) above.

Furthermore, as already discussed above, the claims and specification also satisfy criterion (2) above by defining the soluble RANK polypeptides of section (b) as amended with a disclosed relationship between structure and function. The specification and part (b) of claims 5 and 13 as currently amended state that some soluble RANK polypeptides with RANKL binding activity (a functional activity) are ones that have greater than 90% sequence identity to the specified regions of SEQ ID NO:2 (a structural characteristic). See, also, for example, page 2, lines 13-14 and page 4, lines 30-31.

Additionally, as also pointed out in the last response, claims 5 and 13 are in accord with the type of claim discussed in Example 14 of the "Synopsis of Application of Written Description Guidelines" (Synopsis), a claim which the Patent Office says satisfies the written description requirements. Example 14 is directly analogous to section (b) of claims 5 and 13 as currently amended. The claim in Example 14 reads as follows:

> A protein having SEQ ID NO:3 and variants thereof that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A to B.

Because the claim defines the genus in functional terms that are related to a disclosed correlation between structure and function (see Written Description Guidelines criteria above), the Synopsis concludes that the disclosure meets the written description requirements with respect to this exemplary claim. Part (b) of claims 5 and 13 is in the same format as this claim (i.e., linking functional characteristics to structural

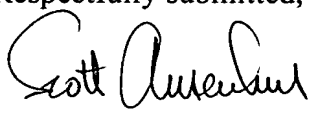
characteristics). As noted above, this relationship is fully supported by the specification. So by analogy, part (b) of currently amended claims 5 and 13 satisfy the written description requirements for the same reasons as the exemplary claim presented in Example 14 of the Synopsis.

It is important to note that in Example 14 of the Synopsis it is assumed that the genus claim in the example is valid even though no variants are specifically exemplified. This is because, as stated in the analysis section of Example 14, procedures for making variants that retain their activity "are conventional in the art." Here, the current specification explicitly defines sequence regions that correspond to the extracellular domain of RANK, which is the region responsible for binding RANKL. The specification also describes assays for detecting binding between the extracellular domain of RANK and RANKL (see, e.g., page 4, line 37 to page 5, line 15 and the examples). It thus would not require undue experimentation to identify further variants as defined in the claims with the same activity.

Thus, for all the foregoing reasons, the specification and currently amended claims satisfy the written description requirements as set forth in the Written Description Guidelines. As such, it is requested that this ground of rejection be withdrawn.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-265-7858.

Respectfully submitted,



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